



UNITED STATES PATENT AND TRADEMARK OFFICE

[Handwritten signature]

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,566	12/05/2003	Cord F. Stahler	2923-593	7975
6449	7590	08/06/2007		
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER SHIBUYA, MARK LANCE	
			ART UNIT 1639	PAPER NUMBER
			NOTIFICATION DATE 08/06/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/727,566	Applicant(s) STAHLER ET AL.	
	Examiner Mark L. Shibuya, Ph.D.	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39 and 41-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39 and 41-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/763,914.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/4/07 and 7/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Application 10727566, (20040175734 A1): Claims 39 and 41-54 are pending and examined.
2. The examiner of record has changed.

Election/Restrictions

3. The requirement for election of species of support and compound being immobilized, set forth in the Requirement for Election of Species, mailed 7/11/2006, is withdrawn. All claims are examined.

Priority

4. This application, 10/727,566, filed 12/5/2003, states that it is a divisional of 09/763,914, filed 5/11/2001, now US Patent 7,097,974, which is the national stage under 35 USC 371 of PCT/EP99/06317, filed 8/27/1999. This application states a claim for foreign priority to Germany priority documents : 1998DE-198 39 254.0, filed 8/28/1998; 1998DE-198 39 255.9, filed 8/28/1998; 1998DE-198 39 256.7, filed 8/28/1998; 1999DE-199 07 080.6, filed 2/19/1999; and 1999DE-199 24 327.1, filed 5/27/1999.

Art Unit: 1639

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/763,914, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claim 49 states the words "information technology links".

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on 1/4/07 and 7/10/07, were filed after the mailing date of the Non-Final rejection on 11/20/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The following claims state the following terms which are not recited in the specification as filed. : Claim 20 states the words “new support”. Claim 21 states the words “negative receptors”. Claim 49 states the words “information technology links”. Correction of the specification is required.

Withdrawn Claim Objection/Rejections

8. The following rejections were withdrawn in view of applicant's arguments and amendments to the claims:

9. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

10. Claims 39-45 and 47-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1639

11. Claims 39 and 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirrung et al. (US Patent 5,142,854).

12. Claims 39 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al. (US Patent 5,142,854) and Fodor et al. (US Patent 5,925,525; *filing date of 04/03/1998*).

13. Claims 39, 42-45, 47, 48, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al. (US Patent 5,142,854) and Wrinkler et al. (US Patent 5,677,195).

14. Claims 39-45, 47, 48, and 50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31 and 37-45 of copending Application No. 10/399,450, i.e. a preliminary amendment was filed in this application wherein claims 1-30 were cancelled and claims 31-60 were added.

This provisional rejection is withdrawn in view of applicant's terminal disclaimer, filed 5/17/2007.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1639

16. Claims 39 and 41-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There appears to be two periods in claim 39. The first period is at the end of line 10, after "support". The second period is at the end of line 19, after "used". Therefore the claim is indefinite.

The term "in any number of positions" in claim 39 is a relative term which renders the claim indefinite. The term "in any number of positions", are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The amended claim, after step (f), recites that an integrated apparatus "is used", but does not state what said integrated apparatus is used for. Thus the omitted steps are: a use for the integrated apparatus. Claims 46, 47, 50 and 52 are similarly rejected for not specifying the use of a planar support, a large number of channels, and a support, respectively; or in the case of claim 52, what the step the reagent kit is "employed" for.

Claim 39 recites the limitation "a support" in line 17. There is uncertain antecedent basis for this limitation in the claim because it is unclear if this the same support as recited in line 2.

Claim 44 recites the limitation "a new support" in line 2. There is uncertain antecedent basis for this limitation in the claim because it is unclear in what way the support is "new".

Claim 45 recites the limitation "negative receptors" in line 3. There is insufficient antecedent basis for this limitation in the claim.

The term "large number" in claims 47 and 50 is a relative term which renders the claim indefinite. The terms "a large number of channels", and "a large number of different receptor", are not defined by claims 47 and 50, respectively, the specification does not provide a standard for ascertaining the requisite degree, and one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 39, 41-46, 48, 49, 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al., US 5,605,662 A.

The claims are drawn to methods for integrated synthesis and analyte determination on a support, comprising the steps of: (a) providing a support body; (b) passing a liquid with, present therein, receptors or building blocks for synthesizing polymeric receptors over a support, (c) site- or/and time-specifically immobilizing the

Art Unit: 1639

receptors or building blocks in each case on predetermined positions on the support, the synthesis and analyte determination being carried out in an integrated apparatus, with the synthesis or/and the analyte determination process being monitored and controlled in any number of positions on the support (d) where appropriate, repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions on the support, (e) bringing the support into contact with a sample containing analytes and (f) determining the analytes via their binding to the receptors immobilized on the support, wherein an integrated apparatus comprising a programmable light source matrix, a detector matrix, a support arranged between light source matrix and detector matrix, and means for supplying fluids into the support and for discharging fluids from the support is used.

Heller et al., throughout the patent and abstract, and at col. 5, line 24-col. 6, line 40, disclose methods of using a microelectronic device for multi-step combination biopolymer synthesis, including oligonucleotides or peptides, (col. 5, lines 31-34). The device is able to control and actively carry out a variety of assays and reactions, and analytes or reactant can be transported to any specific-micro-location. The device has a matrix of specific micro-locations on a matrix on its surface. The device has an associated optical imaging detector system or an integrated sensing component, (col. 5, lines 60-64, col. 7, lines 61-66). Heller et al., state:

In the case of fluorescent binding reactions, it is possible to use an epifluorescent type microscopic detection system for the analysis of the binding reactions. The sensitivity of the system depends on the associated imaging detector element (CCD, ICCD, Microchannel Plate) or photon counting PMT system. One alternative is to associate a sensitive CCD detector or avalanche photodiode (APD) detector directly with the device

Art Unit: 1639

in a sandwich arrangement. Another alternative is to integrate optoelectronic or microelectronics detection in the device.

Heller et al. at col. 20, lines 40-52. The examiner respectfully submits that this disclosure may be reasonably interpreted as disclosing an integrated imaging system, comprising a light source and a detector in a sandwich relationship. The examiner further submits that a reasonable reading of the claim 1 limitation of "a support arranged between light source matrix and detector matrix", includes a support that is arranged between the light of a light source matrix and detector matrix.

Heller et al. disclose a device, as a master device, which can be electronically replicated or copied to another base device (col. 5, line 65- col. 6, line 2; col. 11 line 64- col. 12, line 12). The device can carry out multi-step and multiplex reactions with complete and precise electronic control, preferably with a microprocessor, (Heller et al., at col.s 5-6).

Heller et al., teach various protection and blocking/deblocking steps (e.g., col. 7, line 6-col. 7, line 20; col. 8, line 63-col. 9, line 7, Fig.s 14). Heller et al., at col. 7, lines 22-32, disclose removal of non-specific analytes.

Heller et al., teach micro-locations fabricated on silicon or glass, or plastic, reading on transparent supports, (col. 10, lines 5-44).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1639

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 39 and 41-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al., US 5,605,662 A and Wrinkler et al., US Patent 5,677,195, (of record).

The reference of Heller et al., is relied upon as in the above rejection under 35 USC 102(B).

Heller et al. do not disclose that the support comprises a large number of channels wherein a large number of different receptors are immobilized.

Winkler et al. disclose methods and devices for forming large arrays of polymers on a substrate (see e.g. Abstract; col. 2, lines 15-23, and 55-62). In one method, the method comprises the steps of providing a block having a series of channels that is placed in contact with a substrate; using a delivery system flow selected reagents to one or more of a series of apertures connected to the channels to fill the channels and "striping" the substrate with a first reagent; coupling a first group of monomers onto the substrate wherein the first group of monomers need not be homogenous, i.e. a monomer A may be placed in a first group of the channels, a monomer B in a second group of channels, and a monomer C in a third group of channels; repeating the flowing and coupling steps with a second reagent and coupling a second group of monomers to different regions of the substrate. The process is repeated until a diverse set of polymers of desired sequence and length is formed on the substrate (see e.g. col. 2, lines 31-55; col. 10, line 27 thru col. 13, line 44; figs. 2 and 6-11). In addition, the method includes using the prepared substrate in screening for biological activity wherein the substrate is exposed to a solution of receptor of interest (refers to instant claimed analyte) and detecting the binding of the receptor of interest to the one or more polymers on the substrate (see e.g. col. 17, line 58 thru col. 18, line 6; col. 29, line 52 thru col. 30, line 64). Furthermore, Winkler et al. also disclose that the substrate comprises a series of microchannels (see e.g. col. 2, lines 56-62).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use methods of integrated synthesis and analyte determination on a support, wherein the support comprises a large number of channels

Art Unit: 1639

wherein a large number of different receptors are immobilized as taught by Wrinkler et al.

One of ordinary skill in the art would have been motivated to disclose that the support comprises a large number of channels wherein a large number of different receptors are immobilized in the method of Heller et al. for the advantage of providing independent control of the reaction conditions at different activated regions such that the reactant concentrations and other parameters can be varied independently from reaction site to reaction site (Winkler: col. 8, lines 48-56).

One of ordinary skill in the art would have a reasonable expectation of success in the combination of Heller et al. and Wrinkler et al. because Wrinkler et al. disclose by example the success of the method using support with channels for synthesizing different polymers on the substrate (Winkler: col. 29, line 51 thru col. 30, line 64).

Conclusion

21. Claims 39 and 41-54 are rejected.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya, whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Shibuya, Ph.D.
Primary Examiner
Art Unit 1639